

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/  
FENFLURAMINE/DEXFENFLURAMINE)  
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS  
CORPORATION

CIVIL ACTION NO. 99-20593

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9129

Bartle, J.

August 13, 2013

Lorraine Hart ("Ms. Hart" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether Ms. Hart has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether she met her burden of proving that her claim was not based, in whole or in part, on any intentional material misrepresentation of fact.<sup>2</sup>

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In December, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, W. Marcus Brann, M.D., F.A.C.C., F.A.C.P. Dr. Brann is no stranger to this litigation. According to the Trust, he has signed in excess of 764 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated October 22, 2002, Dr. Brann attested in Part II of claimant's Green Form that Ms. Hart suffered from moderate mitral regurgitation and an abnormal left

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2. (...continued)

medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

atrial dimension.<sup>3</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$496,153.<sup>4</sup>

In the report of claimant's echocardiogram, Dr. Brann stated that Ms. Hart had moderate mitral regurgitation of 24%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Brann also stated that "[t]here is mild left atrial enlargement" and noted that the left atrium measured 56 mm in the supero-inferior dimension and 44 mm in the antero-posterior dimension. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii).

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3. Dr. Brann also attested that claimant suffered from New York Heart Association Functional Class III symptoms. This condition is not at issue in this claim.

4. Under the Settlement Agreement, an eligible class member is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors needed for a Level II claim.

In December, 2005, the Trust forwarded the claim for review by Issam A. Mikati, M.D., F.A.C.C., F.A.H.A., F.A.S.E., one of its auditing cardiologists.<sup>5</sup> In audit, Dr. Mikati concluded that there was a reasonable medical basis for Dr. Brann's findings that claimant had moderate mitral regurgitation and an abnormal left atrial dimension.

Pursuant to Rule 5 of the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Trust undertook "to determine whether there were any intentional material misrepresentations made in connection with the Claim." As part of this review, the Trust engaged Joseph Kisslo, M.D., to review the integrity of echocardiogram system use during the performance of echocardiographic studies and the resulting interpretations submitted in support of certain claims. As stated in his September 19, 2006 declaration, Dr. Kisslo determined, in pertinent part, that:

In Ms. Hart's study, the use of high color gain, high image gain, color persistence, decreased low velocity reject, and color pixels dominant over anatomy, the selection and planimetry of backflow, and the overmeasurement of the mitral "jet," as well

5. The Trust originally forwarded the claim for review by one of its auditing cardiologists in or around March, 2004, who accepted Dr. Brann's findings of moderate mitral regurgitation and an abnormal left atrial dimension. The Trust, however, never issued a determination based on this review because we subsequently imposed a stay on the processing of claims pending implementation of the Seventh Amendment to the Settlement Agreement. After the stay was lifted, we entered Pretrial Order ("PTO") No. 5632, which allowed the Trust to re-audit Matrix claims that were reviewed by auditing cardiologists but for which the Trust had not issued post-audit determinations. The Matrix claims that were subject to re-audit included Ms. Hart's claim.

as the undermeasurement of the left atrial area are the result of deliberate choices and conduct engaged in by the sonographer performing this study and at a minimum, acquiesced in by the Attesting Physician. Each of these manipulations exaggerated or created the appearance of regurgitation or jet duration.

Thus, notwithstanding Dr. Mikati's findings at audit, the Trust issued a post-audit determination denying Ms. Hart's claim based on its conclusion that there was substantial evidence of intentional material misrepresentation of fact in connection with the claim. Pursuant to the Audit Rules, Ms. Hart contested this adverse determination.<sup>6</sup> In contest, claimant noted that she did not dispute the findings of the two auditing cardiologists who determined there was a reasonable medical basis for her claim. Instead, she submitted a letter from Robert E. Fowles, M.D., dated November 21, 2006, wherein he stated that he reviewed claimant's October 22, 2002 echocardiogram and measured the mitral regurgitant jet area to be 23%. Dr. Fowles specifically noted that he took into account Dr. Kisslo's observations and objections but noted that "in the frames I used for determination, I do not find excessive color gain, persistence, tissue encroachment ... [or] detect axial or lateral smoothing."

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Hart's claim.

In addition, Ms. Hart included with her contest a September 8, 2005 letter from Class Counsel to the Trust<sup>7</sup> and a motion filed on behalf of Ms. Hart and several other claimants represented by Ms. Hart's law firm to enforce PTO No. 5632 or to set aside PTO No. 5632 and to compel production of certain Trust documents.<sup>8</sup>

The Trust then issued a final post-audit determination, again denying Ms. Hart's claim. The Trust asserted that Dr. Fowles did not respond to most of the Trust's evidence of intentional material misrepresentations of fact. Specifically, the Trust noted that Dr. Fowles did not respond to Dr. Kisslo's findings that the echocardiographer who performed Ms. Hart's October 22, 2002 echocardiogram "used high color gain, imagine gain, color persistence, color pixel dominance and improperly measured backflow instead of sustained high velocity flow, overtraced the jet beyond its borders and undertraced the left atrial area." The Trust further asserted that in instances where Dr. Fowles did disagree with Dr. Kisslo, he failed to "identify

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7. In this letter, Class Counsel argued, among other things, that the Trust could not deny payment on any claim in which a post-audit determination letter had been sent unless it found that the claim was based on a fraudulent echocardiogram and that the Trust could not rely on the reports of Dr. Kisslo to determine whether a claim in which a post-audit determination letter had been sent was fraudulent. The issues raised in Class Counsel's letter also were the subject of a motion filed by Class Counsel and joined by a number of firms representing various Class Members. Class Counsel and all but one firm subsequently withdrew the motion after the adoption of certain Court Approved Procedures. We denied the motion of the remaining firm following briefing and argument. See PTO No. 6099 (Mar. 31, 2006).

8. We subsequently denied this motion. See Mem. in Supp. of PTO No. 9114, at 6 n.8 (July 23, 2013).

the frames upon which he relied in making those determinations or in reaching his conclusion that [Ms. Hart had] moderate mitral regurgitation." Moreover, the Trust noted that, notwithstanding their differing opinions, Dr. Fowles concluded that "Dr. Kisslo's project is a detailed and painstaking exploration and dissection of ultrasound imaging as applied to the particular issues at hand," which included "an exhaustive systematic analysis of echocardiographic technique and results as portrayed by the commercial imaging company, 'Sound Source.'" The Trust also contended that Class Counsel's letter could not support Ms. Hart's claim for benefits because it did not address the specific facts of her claim and "the primary contentions made by [Class Counsel] in [its] September 8, 2005 letter were actually litigated and have been either settled by CAP No. 11 or denied by the Court in PTO [No.] 6099, both entered on March 31, 2006." Finally, the Trust incorporated and attached the opposition it filed in response to claimants' motion.

Ms. Hart disputed the Trust's final determination and requested that her claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Hart's claim should be paid. On May 14, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7194 (May 14, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master, incorporating by reference the materials she submitted in contest. The Trust did not reply. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>9</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issues presented for resolution of this claim are whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's findings that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension and, if so, whether she also has met her burden of proving that her claim was not based, in whole or in part, on any intentional material misrepresentation of fact. See id. Rule 24. Ultimately, if we determine that there

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.



is no reasonable medical basis for the answers in claimant's Green Form that are at issue or that an intentional material misrepresentation of fact was made in connection with the claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers and that there was not an intentional material misrepresentation of fact made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically, Dr. Vigilante observed:

The color flow portion of the study was of poor quality. There was clear evidence of excessive color gain. There was color artifact noted in the myocardium. In addition, the supposed mitral regurgitation jet consisted of significant color artifact with excessive gain. The Nyquist limits appeared to be appropriately set. However, the low velocity reject was only 2.6 cm per second.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate claimant's echocardiogram and determined that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Dr. Vigilante explained, in pertinent part, that:

There were several supposed regurgitant jet areas measured by the sonographer. These measurements included 5.92 cm<sup>2</sup>, 6.03 cm<sup>2</sup>, 5.13 cm<sup>2</sup>, 5.55 cm<sup>2</sup>, and 5.30 cm<sup>2</sup>. These supposed RJA's are inaccurate. A portion of these measurements include backflow as these measurements were taken during the latter part of the QRS complexes and at the beginning of systole. In real time, the true RJA is much smaller. Visually, the degree of mitral regurgitation appears mild. I digitized those cardiac cycles in the apical four chamber view in which the mitral regurgitation appeared most severe. I was able to accurately planimeter the RJA in the midportion of systole. The largest RJA was 4.1 cm<sup>2</sup> in spite of the excessive color gain. I was able to exclude backflow and low velocity flow artifact in my measurement. The true LAA was 24.0 cm<sup>2</sup>. The measurement of the supposed LAA of 21.1 cm<sup>2</sup> by the sonographer was inaccurate and did not completely include the posterolateral portion of the left atrium. Therefore, the RJA/LAA ratio was no greater than 17.1% in those cardiac cycles in which the mitral regurgitation appeared most severe. The accurately measured RJA/LAA ratio did not come close to approaching 20%.

After reviewing the entire show cause record, we find claimant has not established a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. In the context of those two documents, we previously have explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion

of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation.

See Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26

(Nov. 14, 2002).

Here, Dr. Kisslo and Dr. Vigilante found that claimant's sonographer improperly selected, traced, and measured a supposed regurgitant "jet" that occurred too early in systole and consisted of backflow rather than true high velocity sustained regurgitant flow. In addition, Dr. Vigilante determined that the sonographer improperly included low velocity flow in his measurement of claimant's RJA. Dr. Kisslo and Dr. Vigilante also concluded that the sonographer underestimated claimant's LAA, which artificially increased the level of Ms. Hart's regurgitation. Finally, Dr. Kisslo and Dr. Vigilante found that the echocardiogram of attestation was not conducted in a manner consistent with medical standards because, among other things, the echocardiogram settings included clear evidence of excessive color gain and decreased low velocity reject.

Notwithstanding these deficiencies, Dr. Kisslo and Dr. Vigilante determined that Ms. Hart's echocardiogram demonstrated only mild mitral regurgitation. In addition, Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the attesting physician's opinion

that Ms. Hart had moderate mitral regurgitation.<sup>10</sup> Specifically, he explained that "the RJA/LAA ratio was no greater than 17.1% in those cardiac cycles in which the mitral regurgitation appeared most severe" and that "[t]he accurately measured RJA/LAA ratio did not come close to approaching 20%."

Furthermore, claimant offers little substantive challenge to these findings aside from the largely conclusory opinions of Dr. Fowles. For example, while Dr. Fowles states that he disagrees with Dr. Kisslo's determinations based on the frames he reviewed, he does not identify any particular frame demonstrating any improper conduct. Moreover, although Ms. Hart refers to documents that contend Dr. Kisslo lacked the requisite independence to validate his findings, she makes no such contention against Dr. Vigilante, an independent cardiologist appointed by the court who reached similar conclusions during a separate review. Without identifying some specific error by the Trust's expert and the Technical Advisor, claimant cannot meet her burden of proof in establishing that her claim is payable.

We also reject claimant's argument that she should be paid because her claim passed a second audit pursuant to PTO No. 5632. The plain language of the Audit Rules expressly provides that the Trust must conduct a review separate from the auditing cardiologist with respect to whether there were any intentional material misrepresentations of fact in connection

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10. Despite an opportunity to do so, Ms. Hart did not submit a response to the Technical Advisor Report. See Audit Rule 34.

with a claim. Specifically, the Audit Rules state, in pertinent part, that:

The Auditing Cardiologist shall review a Claim in accordance with these Rules to determine whether there was a reasonable medical basis for each answer in Part II of the GREEN Form that differs from the Auditing Cardiologist's finding on that specific issue ("GREEN Form Question at Issue"). The Trust shall review a Claim to determine whether there were any intentional material misrepresentations made in connection with the Claim. The Trust may consider information from other Claims in Audit to determine the existence of facts or a pattern of misrepresentations implicating intentional misconduct by an attorney and/or physician that may warrant relief pursuant to Section VI.E.8 of the Settlement Agreement.

Audit Rule 5. Based on the findings of Dr. Kisslo, the Trust denied Ms. Hart's claim, determining that the claim was based on one or more intentional material misrepresentations of fact.

Ms. Hart disputed this determination and proceeded to the show cause process. We need not determine whether there was, in fact, any intentional material misrepresentation of fact in connection with Ms. Hart's claim given our conclusion, based on our review of the entire record, that there is no reasonable medical basis for Dr. Brann's representation that claimant had moderate mitral regurgitation.<sup>11</sup>

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11. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625 at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists who determined that there is no reasonable medical basis for a claim simply because the claim has  
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For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Hart's claim for Matrix Benefits.

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11. (...continued)  
previously passed audit.